

Remarks

Claims 2-20 are pending in the application. Claims 6 and 11-13 were objected to. Claims 2-20 were rejected. Claims 2, 3, 6, 8, and 11-13 are amended. Claim 2 is the independent claim. Reconsideration of the amended application in view of the following remarks is respectfully requested.

The examiner objected to claims 6 and 11-13 because of certain noted informalities. The claims are amended to address these informalities. The objection, therefore, should be withdrawn.

The examiner rejected claims 2-20 under 35 USC §112 as being indefinite. Claim 2 is amended to address the examiner's comments. The rejection, therefore, should be withdrawn. Regarding claim 2, that claim recites that the determination whether to augment the input data set and/or the outcome data set is made according to predetermined criteria, establishing the necessary metes and bounds of the claim. Further, the step of augmenting the input data of each subject by its propensity score data and/or its stratum assignment according to predetermined criteria is independent of the previous augmenting step, and therefore the previous optional augmenting of the input data set has no bearing on this step.

The examiner rejected claims 2-16, 19, and 20 under 35 USC §101 as being directed to non-statutory subject matter. The claims were previously amended such that they are statutory under *Ex parte Bliski*, by tying the claimed method to a particular machine or apparatus. For example, claim 2 was previously amended to recite that the training step was performed through the use of a computing device. The claims are

further amended herein to limit the learning-capable system to an artificial learning-capable system, obviating the possibility that this system could be a human being. The rejection, therefore, should be withdrawn.

The examiner rejected claims 2-9 and 11-20 under 35 USC §102(b) as being anticipated by Barnhill et al.

As amended, independent claim 2 recites a method for training at least one artificial learning-capable system. The claimed method includes providing a predetermined training data set corresponding to predetermined number of subjects comprising a predetermined input data set and a predetermined outcome data set, and augmenting the input data set and/or the outcome data set according to predetermined criteria. Survival data relating to patient survival of J subjects is observed. Covariates denoted $x_{q(j)}$ are recorded at a reference time $t=0$, $q=1, \dots, Q$ (in vector notation $\mathbf{x}(j)$), $j=1, \dots, J$, referring to the subject number in any order. Special covariates denoted $z_p(j)$, $p=1, \dots, P$ (vector notation $\mathbf{z}(j)$) are recorded. Each subject is assumed to represent a random sample drawn from a large pool of subjects with identical covariates \mathbf{x} , \mathbf{z} , defining the conditional probability $S(t|\mathbf{x}, \mathbf{z})$ for surviving to time t given \mathbf{x} , \mathbf{z} . The p -th propensity score $\phi_p(\mathbf{x}(j))$ is estimated of subject j for treatment p corresponding to the probability for subject j to have treatment $z_p=1$. The propensity scores are categorized into a number N_p of categories, designated as strata. The input data set is augmented by the propensity scores and/or the stratum categorization. Each artificial learning-capable system is trained using the input data set and/or the outcome data set that was augmented according to the augmenting step, through the use of a computing device. It is noted that

a “propensity score” is a well-known and defined term of art in the field of statistics used, for example, to reduce selection bias.

Thus, claim 2 is amended to add details of the training hazard model of the present invention, as disclosed in the original specification on pages 41-44. The augmenting step is defined in more detail, as are the propensity scoring and the categorization of the propensity scores into a number of categories designate as strata. The data of each subject is augmented by its propensity score and the artificial learning-capable system is trained using the augmented data set, through the use of a computing device.

Claim 3 is amended to recite the method according to claim 2, and further defines the optimization aspect of the training step, referring to operating point parameters of the artificial learning-capable system within each stratum. According to claim 3, operating point parameters are optimized within each stratum. The operating point corrections OP_{kl} ($\varphi_1, \varphi_2, \dots, \varphi_P$) are determined for shifting the output of the neural network $NN_k(\mathbf{X})$ with $\mathbf{X}=\{\mathbf{x}, \mathbf{z}\}$, provided by the neural network, given the propensity scores $\varphi_1, \varphi_2, \dots, \varphi_P$, considering a hazard model $\lambda_k(t | \mathbf{X}) = \lambda_{k0}(t)h_k(t | \mathbf{X}, \varphi_1, \varphi_2, \dots, \varphi_P)$. In the claim, k denotes the k -th outcome and the hazard is decomposed as $h_k(t | \mathbf{X}, \varphi_1, \varphi_2, \dots, \varphi_P) = \exp[\sum_{i=1}^k B_i(t)(NN_k(\mathbf{X}) - OP_{kl}(\varphi_1, \varphi_2, \dots, \varphi_P))]$. $B_i(t)$ are suitable functions comprising the time dependence.

Barnhill et al. do not disclose or suggest the invention as recited in the claims as amended, and thus do not anticipate the invention as recited in claim 2. Claims 3-9 and

11-20 depend from claim 2, and therefore also are not anticipated by Barnhill et al. The rejection of claims 2-9 and 11-20, therefore, should be withdrawn.

It is submitted that all objections and rejections have been overcome. It is therefore requested that the Amendment be entered, the claims allowed, and the case passed to issue. If any issues remain after entry of this Amendment, the examiner is urged to contact the undersigned by telephone to expedite resolution.

Respectfully submitted,



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